PATENT COOPERATION TREATY

21 JAN. 2004

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

(5)

WRITTEN OPINION
(PCT Rule 66)

Date of mailing *(day/month/year)*	16.01.2004
Applicant's or agent's file reference 000711-0024	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA 03/00487	03.04.2003	05.04.2002

International Patent Classification (IPC) or both national classification and IPC
C08G63/06

Applicant
UNIVERSITE DE MONTREAL et al

1. This written opinion is the ~~first~~ second drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 05.08.2004

Name and mailing address of the international preliminary examining authority:

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Authorized Officer
Zeslawski, W

Formalities officer (incl. extension of time limits)
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I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

3, 4, 6, 8, 9, 11, 15	as originally filed
1, 2, 5, 7, 10, 12-14	filed with telefax on 03.11.2003

Claims, Numbers

1-16	as originally filed

Drawings, Sheets

2/5-5/5	as originally filed
1/5	filed with telefax on 03.11.2003

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-4,6,13,14,16: No; 5,7-12,15: Yes
Inventive step (IS)	Claims	1-7,13-16: No; 8-12:Yes
Industrial applicability (IA)	Claims	1-16: Yes

2. Citations and explanations

see separate sheet

Reference is made to the following document:

D1: WO-A-03000766

Concerning Point V:

Amendments (Art.34(2b) PCT)

The amendments concerning: page 1, l.27; page 2, l.18, page 7, l.6; page 14, l. 29 do not fulfill the requirements of Article 34(2b) PCT since there are no basic in the originally filed description.

The amendments concerning: page 5, l.5; page 7, l.21; page 10 l.7; p.12 l.14 and 17; page 13 l.13 and page 1/5 fulfill the requirements of Article 34(2b) PCT.

Novelty (Art.33(2) PCT)

Document D1 discloses copolymers derived from cyclic esters and epoxides (claim 25), wherein the epoxide is an epoxy compound with a functional group , e.g. a fatty acid, a fatty alcohol, PEG (claim 29) or a group having an unsaturated functionality (claim 30). Furthermore, said functional group can be selected from a group consisting of peptides or lipids (claim 29). The polymer of D1 can easily encapsulate an biologically active agent and facilitate its delivery (par.[127]-[130]).

Consequently the subject matter of claims 1-4,7, 13, 14 and 16 is not novel.

The subject matter of claims 8-12 concerning the method for preparing the polymer of the general formula I of the present application is not disclosed in prior art documents and is regarded as being novel.

Inventive Step (Art.33(3) PCT)

It appears to be no indication in prior art documents to use a special reaction sequence in order to convert lateral ethylenically unsaturated the end group of a polymer into a group having hydroxyl or carboxylic acid functionality as claimed in claim 8. Therefore, the subject matter of claims 8-12 is regarded as inventive.

Providing an amended main claim which meets the requirements of Art. 33(2)PCT, the applicant should relate the distinguishing feature to a surprising (unexpected) technical effect or make credible or plausible that the distinguishing feature is not derivable from the prior art teaching.

Miscellaneous

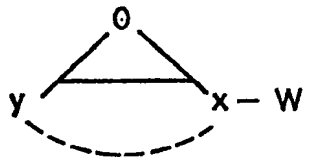
The back reference to claim 6 in claim 7 is incorrect. When an alkyl glycidyl ether is the monomer B, then the compound II has a W-group being different from CH_2CH_2OH or

CH_2COOH group. Moreover, said monomer is not mentioned in the description. Consequently the resulting polymer having copolymerised this monomer seems to be outside the concept of the present application.
Page 2/5 and the first formula on page 5/5 of drawings seems to be incomplete.

4. The functionalizable polymer of formula I as claimed in claim 3, wherein the monomer A is selected from the group consisting of caprolactone, glycolide, dilactide and glycolic lactide.

5. The functionalizable polymer of formula I as claimed in claim 1 or 2, wherein Z is -NH- and the monomer A is selected from the group consisting of lactams and dilactams.

6. The functionalizable polymer of formula I as claimed in any one of claims 1 to 5, wherein the monomer B is selected from the group consisting of the epoxides of formula II:



(II)

wherein:

X is a non-functional chain optionally containing one or more heteroatoms but no ester or amide link;

W is - CH_2CH_2OH or -CH_2COOH; and

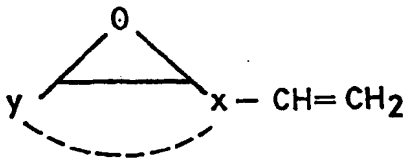
Y is H, alkyl or phenyl;

X and Y being optionally linked to each other as shown in dotted lines.

7. The functionalizable polymer of formula I as claimed in claim 6, wherein the monomer B consists of alkyl glycidyl ether.

8. A process for preparing a functionalizable polymer of formula I as defined in any one of claims 1 to 7, comprising the steps of:

a) reacting at least one monomer A as defined in claim 1, 3 or 4 with at least one epoxide of formula III



(III)